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Date: 7/29/2009 12:32:14 PM

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Fax Contains: 10 pages *(including this sheet)*. If incomplete, please contact sender.

Subject:
U.S. Patent Application No. 09/825,533 - Attorney Docket No. 31886-705.201 - Agenda for Interview scheduled July 30, 2009 at 3:30 pm

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Attached please find the 8-page Agenda for Interview scheduled July 30, 2009 at 3:30 p.m. in connection with the following application:

In re Application:		Confirmation No.:	**9781**
Inventor:	Michael R. Hufford, et al.	Examiner:	Martin A. Gottschalk
Application No.:	09/825,533	Group Art Unit:	3696
Filed:	April 2, 2001	Customer No.	**21971**
Title:	**SYSTEM FOR CLINICAL TRIAL SUBJECT COMPLIANCE**		

PATENT
Attorney Docket No. 31886-705.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application:		Confirmation No.:	**9781**
Inventor:	Michael R. Hufford, et al.	Examiner:	Martin A. Gottschalk
Application No.:	09/825,533	Group Art Unit:	3690
Filed:	April 2, 2001	Customer No.	**21971**
Title:	**SYSTEM FOR CLINICAL TRIAL SUBJECT COMPLIANCE**		

DO NOT ENTER

This communication outlines the agenda for the interview scheduled with Martin A. Gottschalk at 3:30 on July 30, 2009. Applicant's representatives attending the interview will be Louis D. Lieto and Esther Kepplinger.

Agenda: discuss the claims filed on July 2, 2009 in view of the prior rejections and the IDS submission of June 22, 2009.

CLAIMS:

Claims 1-3 (Cancelled)

4. (Currently Amended) A method of determining preferred targets for subject compliance during a current clinical trial, comprising the steps of:

providing at least one of the group of historical subject compliance data and historical protocol data from a previous clinical trial; ~~and~~

generating at least one preferred compliance threshold for the use during the current clinical trial by quantitative analysis of at least one of the group of the historical subject compliance data and the historical protocol data from the previous clinical trial; and

obtaining subject compliance information during the current clinical trial comprising using a portable electronic device capable of displaying information and receiving and storing input from a user to obtain said subject compliance information; and

comparing the subject compliance information to the at least one preferred compliance threshold to determine if action is needed.

5. (Canceled)

6. (Currently Amended) The method of determining preferred targets for subject compliance of claim ~~5~~ 4, further comprising the step of prompting action if the step of comparing indicates that action is needed.

7. (Canceled)

8. (Currently Amended) A method of monitoring subject compliance during a current clinical trial, comprising the steps of:

providing historical subject compliance data from a previous clinical trial;

generating at least one algorithm reflective of the historical subject compliance data by quantitative analysis of the historical subject compliance data;

translating the at least one algorithm into at least one decision rule for analyzing subject compliance information;

obtaining the subject compliance information during the current clinical trial, comprising using a portable electronic device capable of displaying information and receiving and storing input from a user to obtain said subject compliance information;

comparing the subject compliance information to the at least one decision rule to determine if corrective action is needed; and

prompting corrective action if the step of comparing indicates that corrective action is needed.

9. (Original) The method of predicting subject noncompliance of claim 8, wherein said step of providing includes providing historical protocol data and wherein said step of generating includes quantitative analysis of the historical protocol data.

10. (Original) The method of determining subject compliance of claim 9, wherein the step of providing employs at least one database containing the historical protocol data.

11. (Canceled)

12. (Original) The method of determining subject compliance of claim 8, wherein the step of generating employs at least one of the group of multiple linear regression, discriminant function analysis, logistic regression, neural networks, classification trees and regression trees.

13. (Original) The method of determining subject compliance of claim 8, wherein the step of providing employs at least one database containing the historical subject compliance data.

14. (Currently Amended) A method of determining subject compliance during a current clinical trial; comprising the steps of:

providing historical subject compliance data and historical protocol data from a previous clinical trial;

generating a spectrum of compliance representative of the historical subject compliance data not compliant with the historical protocol data by quantitative analysis of the historical subject compliance data and the historical protocol data;

obtaining subject compliance information during the current clinical trial, comprising using a portable electronic device capable of displaying information and receiving and storing input from a user to obtain said subject compliance information;

comparing the spectrum of compliance to the subject compliance information to determine if corrective action is needed; and

prompting corrective action if the step of comparing indicates that corrective action is needed.

15. (Canceled)

16. (Currently Amended) A method of predicting subject noncompliance during a current clinical trial, comprising the steps of:

providing historical subject compliance data from a previous clinical trial;

generating at least one predictive algorithm for predicting subject noncompliance by quantitative analysis of the historical subject compliance data;

translating the at least one predictive algorithm into at least one prediction rule for use during the current clinical trial;

obtaining subject compliance information during the current clinical trial comprising using a portable electronic device capable of displaying information and receiving and storing input from a user to obtain said subject compliance information;

comparing the subject compliance information to the at least one prediction rule to determine if action is needed; and

prompting action if the step of comparing indicates that action is needed.

17. (Original) The method of predicting subject noncompliance of claim 16, wherein said step of providing includes providing historical protocol data and wherein said step of generating includes quantitative analysis of the historical protocol data.

18. (Original) The method of determining subject noncompliance of claim 17, wherein the step of providing employs at least one database containing the historical protocol data.

19. (Canceled)

20. (Original) The method of predicting subject noncompliance of claim 16, further comprising the step of creating an evaluability database adapted to store data related to subject compliance.

21. (Previously Presented) The method of predicting subject noncompliance of claim 20, further comprising the step of providing access to the evaluability database to a sponsor to allow the sponsor to make a determination regarding a subject based on data from the evaluability database.

22. (Previously Presented) The method of predicting subject noncompliance of claim 20, wherein the evaluability database is tailored to a condition affecting the subject.

23. (Original) The method of determining subject noncompliance of claim 16, wherein the step of providing employs at least one database containing the historical subject compliance data.

24. (Currently Amended) A method of enhancing subject compliance during a current clinical trial, comprising the steps of:

providing historical subject compliance data from a previous clinical trial;

generating at least one algorithm by quantitative analysis of the historical subject compliance data;

translating the at least one algorithm into at least one decision rule for using during the current clinical trial;

obtaining subject compliance information; and

comparing the subject compliance information to the at least one decision rule on a portable electronic device or a computer to determine if affirmative action is warranted.

25. (Original) The method of predicting subject noncompliance of claim 24, wherein said step of providing includes providing historical protocol data and wherein said step of generating includes quantitative analysis of the historical protocol data.

26. (Original) The method of enhancing subject compliance of claim 24, further comprising the step of prompting action if the step of comparing indicates that affirmative action is warranted.

27. (Original) The method of enhancing subject compliance of claim 24, wherein the affirmative action includes reducing a number of occurrences of the step of obtaining subject compliance information.

28. (Original) The method of enhancing subject compliance of claim 24, wherein the affirmative action includes increasing a number of occurrences of the step of obtaining subject compliance information.

29. (Original) The method of enhancing subject compliance of claim 24, wherein the affirmative action includes giving a reward.

30. (Original) The method of enhancing subject compliance of claim 24, wherein the step of obtaining includes the use of a portable electronic device capable of displaying information and receiving and storing input from a user.

Claims 31-47 (Cancelled)

48. (Currently Amended) A computer readable medium suitable for use in an electronic device and having instructions recorded thereon for execution on the electronic device, the instructions comprising the steps of:

providing at least one of the group of historical subject compliance data and historical protocol data from a previous clinical trial; and

generating at least one preferred compliance threshold for the use during a current clinical trial by quantitative analysis of at least one of the group of the historical subject compliance data and the historical protocol data from a previous clinical trial.

49. (Currently Amended) A computer readable medium suitable for use in an electronic device and having instructions recorded thereon for execution on the electronic device, the instructions comprising the steps of:

providing historical subject compliance data from a previous clinical trial;

generating at least one algorithm reflective of the historical subject compliance data by quantitative analysis of the historical subject compliance data;

translating the at least one algorithm into at least one decision rule for analyzing subject compliance information during a current clinical trial;

obtaining the subject compliance information during the current clinical trial;

comparing the subject compliance information to the at least one decision rule to determine if corrective action is needed; and

prompting corrective action if the step of comparing indicates that corrective action is needed.

50. (Currently Amended) A computer readable medium suitable for use in an electronic device and having instructions recorded thereon for execution on the electronic device, the instructions comprising the steps of:

providing historical subject compliance data and historical protocol data from a previous clinical trial;

generating a spectrum of compliance representative of the historical subject compliance data not compliant with the historical protocol data by quantitative analysis of the historical subject compliance data and the historical protocol data;

obtaining subject compliance information during a current clinical trial;

comparing the spectrum of compliance to the subject compliance information to determine if corrective action is needed; and

prompting corrective action if the step of comparing indicates that corrective action is needed.

51. (Currently Amended) A computer readable medium suitable for use in an electronic device and having instructions recorded thereon for execution on the electronic device, the instructions comprising the steps of:

providing historical subject compliance data from a previous clinical trial;

generating at least one predictive algorithm for predicting subject noncompliance by quantitative analysis of the historical subject compliance data;

translating the at least one predictive algorithm into at least one prediction rule for use during a current clinical trial;

obtaining subject compliance information during the current clinical trial;

comparing the subject compliance information to the at least one prediction rule to determine if action is needed; and

prompting action if the step of comparing indicates that action is needed.

52. (Currently Amended) A computer readable medium suitable for use in an electronic device and having instructions recorded thereon for execution on the electronic device, the instructions comprising the steps of:

providing historical subject compliance data from a previous clinical trial;

generating at least one algorithm by quantitative analysis of the historical subject compliance data;

translating the at least one algorithm into at least one decision rule for use during a current clinical trial;

obtaining subject compliance information during the current clinical trial; and

comparing the subject compliance information to the at least one decision rule to determine if affirmative action is warranted.

53. (Cancelled)

REMARKS

Claims 4, 6, 8, 14, 16, 24, and 48-52 are currently amended. Claims 5, 7, 11, 15 and 19 are canceled. Claims 4, 6, 8-10, 12-14, 16-18, 20-30, and 48-52 are currently pending. Reconsideration of the application in view of the current claims is respectfully requested and further in view of the following Remarks.

Amendments to the Claims

The amendments to the claims are supported throughout the original specification as filed and introduce no new matter. For example:

Claims 4 and 6: Original claims 5 and 7, paragraph 39.
Claim 8, 14 and 16: Original claim 11, 15 and 19, paragraph 39.
Claim 24: Paragraph 63.
Claims 48-52: Paragraph 84.